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Position Paper on AmCham EU Areas of Concerns and Priority Issues for the European Commission's REACH Proposal as amended by the European Council and the European Parliament

EXECUTIVE SUMMARY

1. The "Candidate List" of substances of Very High Concern under REACH and its expected "Black List" effect

The Council and the Parliament are proposing to publish the list of substances that meet the criteria to be classified as "substances of very high concern" under the Authorisation process (the so-called "candidate list") and the notification to the Chemicals Agency of candidate list substances when present in "articles" above 0.1%. Identifying the presence of candidate list substances in all articles being produced and imported into the EU and notifying them when they meet the notification criteria will create a huge unnecessary burden across the whole spectrum of the Industry. Also, the mere publication of the candidate list will have a *de facto* "black list effect" that is likely to cause massive product reformulations, business disruptions and unnecessary barriers to trade before the risks of these substances are assessed under REACH. This would constitute a breach of the principle of proportionality and is an "unnecessary obstacle" to trade pursuant to article 2.2 of the WTO Agreement on technical barriers to trade (TBT). AmCham EU is strongly opposed to the elaboration and publication of a "candidate list" and to that list serving as a reference for purposes of notifying substances in articles.

2. Monomers in Imported Polymers

As proposed by the Commission and supported by the Council, manufacturers or importers of polymers would need to register monomers used in the production of those polymers if they have not been previously registered, if each monomer represents at least two percent of the polymer and if the monomer is imported in quantities of at least one tonne per year. In concrete terms, this means that the EU would require Registration for substances (monomers) that have been converted into polymers outside the EU. Despite there being no human or environmental exposure to such monomers in the EU in the life cycle stages during which the monomers existed in unreacted form. Therefore, the cost of registration significantly and disproportionately outweighs the environmental and health benefits. In order to facilitate the registration, a non-EU polymer manufacturer will have to disclose to the EU importer confidential business information about the identity of the monomers used. Again this is disproportionate to the insignificant human and environmental benefits and therefore presents a technical barrier to trade under the WTO TBT Agreement. AmCham EU supports the amendment tabled by the European Parliament that would require only the "notification" of monomers in polymers, but would allow the Chemicals Agency to

come back to the monomer manufacturer to request more information and submit a complete registration dossier in case of concern. Registration would be required up front for those monomers imported in quantities above 1000 tonnes a year.

3. The implications of Consumer Information Provisions under REACH

In 1st Reading, the European Parliament introduced new obligations into the REACH proposal requiring article manufacturers to provide consumers with information on the chemical content of articles. These obligations are not necessary and should not be reintroduced in 2nd Reading. These include the right of consumers to ask for "information on the substances present" in the article, the possible development of a "quality mark" identifying articles that were manufactured in complete conformity with REACH and information to use articles safely when they contain a "candidate list" substance. AmCham EU believes that no further consumer information requirements should be introduced in REACH for articles. The General Product Safety Directive (2001/95/EC) already requires manufacturers and importers of articles to provide consumers with the information necessary to enable them to assess risks and to take precautions against those risks. Labelling and consumer information requirements are also further elaborated in vertical sector legislation and in schemes for the management of waste. If further information is needed, this should be specified as appropriate in vertical legislation.

4. Authorisation Issues – Substitution and Time Limits

The European Parliament (article 52) has proposed that, as a matter of principle, REACH should apply a "substitution" requirement for substances subject to Authorisation. Therefore, risk assessment and adequate risk management are not considered as being enough. This infringes the fundamental principle of the safe use of substances. Also, the European Parliament has proposed a time-limited Authorisation of five years whereby 18 months before expiry, a new application for Authorisation would need to be made; otherwise Authorisations become invalid automatically. This time limitation would not encourage the innovation of safer substitutes, a key objective of REACH. AmCham EU believes that the European Parliament should not reintroduce the elements of its 1st Reading on Authorisation in 2nd Reading.

ANALYSIS

1. The "Candidate List" of Substances of Very High Concern under REACH and its Expected "Black List" Effect (article 6.2)

<u>Authorisation</u>

The Commission Proposal on REACH established a procedure whereby a given number of "substances of very high concern" (SVHC)[1], generally estimated at 25-30,

[1] Substances of Very High Concern are substances that meet the criteria for carcinogenic, mutagenic and reproductive toxic (CMR) substances of category 1 and 2, persistent, bioaccumulative and toxic (PBT) substances, very persistent and very bioaccumulative (vPvB) substances, and other substances raising equivalent concerns.

would be identified every year that require Authorisation to be maintained on (or gives access to) the EU market. This is maintained, but both the Parliament and the Council[2] have added a preliminary step whereby a "candidate list" of substances that are considered to meet the SVHC criteria will first be elaborated and published on the Chemical Agency's website. It is expected that this "candidate list" will be published by the end of 2008 on the basis of substances nominated by Member State authorities and may contain up to 1500 substances. It is from this list that a prioritisation mechanism will be set up every year to identify the 25-30 substances that will be subject to Authorisation.

Substances in Articles

The Commission Proposal exempted from Registration, substances in articles, except if they were intended or known to be released from these articles in specific conditions. While Registration for intended release remains, the Parliament and the Council[3] are proposing that there is no longer a Registration obligation for unintended release. Instead, what matters would be whether articles "contain" more than 0.1% of any of the substances listed on the "candidate list" for Authorisation, in which case the producers or importers of the articles will need to "notify" information on these substances to the Agency (ie, identity of producer/importer, registration status, classification and labelling and article use), within a very short delay (currently, three to six months from listing on the "candidate list"), except for substances that have already been registered for that specific article use. The Agency can then require Registration for these substances in certain conditions.

In reality, notification will mainly affect articles imported into the EU, because articles produced in the EU could only be made with previously registered substances. Also, in view of the sheer number of articles produced and imported into the EU, it will simply be impossible for authorities to enforce the proposed requirement and achieve a level playing field.

The Black List Effect

Furthermore, when the "Candidate List" is published, it is expected/feared that this list will be used by green NGOs and their Governmental supporters to force companies to not use these substances before they have an opportunity to be authorised and while REACH allows for their lawful use.

Indeed, it will be very difficult, in particular for companies making consumer products (eg, toys, food packaging and cosmetics), but potentially for many other companies (eg, those producing cars and computers) to justify the presence of "substances of very high concern" in their products and they will therefore require their suppliers to only supply raw materials that are free of candidate list substances.

Considering the complexity of some of the supply chains and long "time to market", the product reformulations that this black list effect will generate is likely to be massive, causing major business disruptions and unnecessary barriers to trade while the risks posed by candidate list substances have yet to be assessed under REACH.

[2] Article 56.1 of the Council Political Agreement
[3] Article 6.2 of the Council Political Agreement

More specifically, the creation of a "candidate list" with substances that have not yet been tested in a proper and thorough scientific procedure means that substances are put on this list without any prior proof of their environmental or health risks. Putting a substance on the "candidate list" is not simply a preparatory step for further decision-making, but will have immediate commercial consequences. The "candidate list" will create a pre-emptive effect, putting heavy burdens on the use of these substances even before they have been assessed through a proper and thorough scientific procedure. Certain substances will thus be pushed out of the market before any proof of their environmental and health risks is established. This constitutes a breach of the principle of proportionality and is an "unnecessary obstacle" to trade pursuant to article 2.2 of the WTO Agreement on technical barriers to trade (TBT).

AmCham EU Proposal

While AmCham EU would prefer that substances in articles be completely exempt from the scope of REACH unless there is intentional release, a possible alternative would be to not require the Agency to set up and publish a "candidate list" and to only publish annually the list of priority substances of very high concern that will be subject to Authorisation. Producers and importers of articles could then be required to notify the agency if their products contain one of these substances above given thresholds and if the other conditions proposed by the European Council are met (ie, above one tonne per year and exposure to man and the environment cannot be excluded). By doing so they would provide information directly relevant to the Authorisation process but without the dramatic economic consequences that the "candidate list" may have.

2. Monomers in Imported Polymers

Issue

As proposed by the Commission and supported by the Council, REACH Article 5 paragraph 3 requires manufacturers or importers of polymers[4] to register monomer[5] substances used in the production of those polymers if they have not been previously registered, if each monomer represents at least two percent of the polymer, and if the

[4] *A polymer is generally a large molecule that is made up of reacted monomers and has special chemical and physical properties that are different from the properties of the monomers it is made of. A polymer has a high molecular weight. Examples of polymers include plastics (polymers with colorants and stabilizers) used for water bottles or traffic lights, mobile phones ,ink, parts for car interior, window films, adhesives. Polymers are usually considered to be of low risk, which is one of the reasons for exempting them from REACH registration requirements.*

Polymer producers are both knowledgeable and skilled in managing the hazards and risks associated to monomers when reacting them to produce polymers.

Example: "ethylene" monomer is a hazardous gas used to make polyethylene, which is not hazardous. Polyethylene is used to make plastic shopping bags.

[5] *A monomer is a small and reactive molecule that can link together to form large, stable molecules called polymers. Monomers are reactive chemical species designed to form solid bonds. When monomers are reacted with each other to form a polymer (reacted monomers), their reactive or hazardous properties are consumed. Monomers are normally no longer present in the resulting polymers.*

monomer is imported in quantities of at least one tonne per year.

The proposed requirement supported by the Council would in effect impose disproportionate measures that would have the following implications:

- the registration of substances that are converted in generally harmless substances outside the EU: importing a polymer does not contribute to human and environmental exposure to the monomer in the EU. As such, the monomers and their original chemical properties no longer exist when the polymer is imported;

- registration costs that would significantly and disproportionately outweigh the environmental and health benefits: reacted monomers are generally no longer readily bio-available as they are covalently bound to form the polymer. As such they have low risk potential, which is why polymers are exempted from registration requirements;

- the disclosure of confidential business information in order to be able to present a complete registration dossier: the registration requirement would compel importers to request foreign polymer producers to provide information on the composition of the polymer, which may be considered by the producer as protected intellectual property and
- the raising of potential technical barriers to trade: the WTO TBT Agreement tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. Requiring registration of substances (monomers) not manufactured, imported or marketed in the EU in order to market a different substance (polymers) may be contrary to the WTO agreement.

AmCham EU Proposal

In its 1st Reading, the European Parliament recognised that Article 5.3, as currently drafted, raises issues of workability and a level playing field. The system suggested by the European Parliament is the notification of monomers in polymers, which allows the Chemicals Agency to come back to the monomer manufacturer to request more information and for them to submit a complete registration dossier in case of concerns. For those monomers that are imported in quantities above 1000 tonnes a year, registration would be required. AmCham EU strongly requires that amendment to be re-tabled and adopted.

3. The implications of Consumer Information Provisions under REACH

In 1st Reading, the European Parliament introduced into the REACH proposal new obligations on article manufacturers to provide consumers with information on the chemical content of articles, as follows:

Consumers' right to information

The Parliament is seeking to grant to consumers the right to ask for "information on the substances present" in the article. This right is supplemented by an obligation on article manufacturers to respond within 15 days to consumer requests for full details on safety and use information concerning the substances present in any article.

The REACH quality mark

The Parliament has asked that, if appropriate, within two years of the entry into force of REACH, the Commission should submit a proposal for a "quality mark" identifying articles that were manufactured in complete conformity with REACH. This proposal is potentially a technical barrier to trade, since only articles manufactured within Europe would be regulated by REACH throughout the manufacturing process. Products manufactured in other countries would be required conform to the legislation of that country; although the imported article would of course conform to REACH.

Information on chemicals on the "Candidate List"

Unlike the Parliament, the Council has proposed no requirement to inform the consumer. Nevertheless, it has introduced an obligation that would require any producer/importer of an article that contains a chemical listed in the "candidate list" above 0.1% w/w (See Section 1 above) to provide the recipient of that article with sufficient information to use the article safely, and as a minimum the name of the chemical. This obligation applies for all recipients of articles in the supply chain. Potentially this includes consumers, as well, which would be one step too far.

AmCham EU Proposal

AmCham EU believes that no further consumer information requirements should be introduced in REACH for articles. The information of value to the consumer relates to the risk they may be exposed to. The General Product Safety Directive (2001/95/EC) already requires manufacturers and importers of articles to provide consumers with the information necessary to enable them to assess the risks and to take precautions against those risks. Labelling and consumer information requirements are also further elaborated in vertical sector legislation and in schemes for the management of waste. If further information is needed, this should be specified as appropriate in vertical legislation.

By contrast, the Parliament is asking for *risk-based* labelling for substances and preparations. AmCham EU fully supports this request as this will provide the consumers with relevant information, provided this is limited to substances and preparations and not extended to articles.

4. Authorisation Issues – Substitution and Time Limits

The Authorisation Process

Through the Authorisation process, REACH will specify which substances deemed to be of very high concern are granted licenses (authorised) or are banned from being placed on the EU market. Substances of very high concern are persistent, bioaccumulative and toxic (PBTs) substances; very persistent and very bioaccumulative (vPvBs) substances; carcinogens, mutagens, reproductive toxicants of category 1 and 2; and endocrine disruptors. Substances at risk under the Authorisation process are substances that could both be produced by chemical companies and used by downstream users either in manufacture, or present in a finished product. It is therefore important that the Authorisation process is risk-based and that legal clarity is given to users or providers of substances at risk of Authorisation.

Substitution

The European Parliament (article 52) has proposed that, as a matter of principle, REACH should apply a substitution requirement for substances subject to Authorisation. Therefore, risk assessment and adequate risk management are not considered as being enough. This infringes the fundamental principle of the safe use of substances. The Council, on the other hand, deletes this duty of substitution and proposes that successful authorisation claims must have provided an analysis of substitution options. The issue of substitution will be revisited on a case-by-case basis within the review procedures of Authorisation (Art. 59 (4)). The case-by-case consideration of authorisations is welcome. Authorisations may be reviewed if new information on possible substitutes is provided to the Agency by a third party.

Time Limits

Parliament has proposed a time-limited Authorisation of five years whereby 18 months before expiry, a new application for Authorisation would need to be made; otherwise Authorisations become invalid automatically (Art. 57, paragraph 6). This time limitation of Authorisations would not encourage the innovation of safer substitutes, one of REACH's goals. It would be damaging for chemical companies as it hits at the heart of innovation in the chemical sector and it would create a risky investment environment for product manufacturers where there would be the potential for a substance key to manufacture would be at risk of being removed from the market.

"Adequate Control"

Article 57 (2bis) of the Council proposal prohibits authorisation on the basis of adequate control of risks for certain substances. Article 57 (2bis) would prohibit the use of substances without consideration of whether the substance comes in contact with human beings or the environment. The cost will be high as industry effectively will be required to abandon use of PBT, vPvB, CMR 1 and 2 and substances of "equivalent concern" - even where there is no contact. This places a huge burden on industry, but provides almost no benefit to human health or the environment.

Specifically, Article 57 (2bis) would ignore the protection provided by the Integrated Pollution Prevention and Control Directive (96/61/EC of 24 September 1996), under which the EU institutions have established a sophisticated system to minimise pollution from installations and to require the installation of Best Available Technology (BAT). The control of emissions from facilities would no longer be sufficient to authorise uses, for example, of PBT or vPvB substances. Moreover, Article 57(2bis) would have the unintended consequence of removing incentives for industrial users to invest in control technologies and "design for the environment" in ways that minimise exposure as there will be no benefit for those actions under REACH.

AmCham EU Proposal

AmCham EU believes that the European Parliament should not reintroduce in 2nd Reading the following elements of its 1st Reading on Authorisation:

- Article 52 setting out the aims of Title VII as being "underpinned by the precautionary principle"

- Article 53a (new), which proposes a new Annex XIIIa ("blacklist" of substances) listing all substances that are known to fulfill the criteria of Article 54.
- Article 54 f on endocrine disruptors and substances of similar concern.
- Article 55, especially inclusion of maximum five year time limits for authorisations.
- Article 56, paragraph 7 proposing qualified majority in Member State Committee for inclusion of substances on Annex XIIIb and for inclusion of substances in Annex XIIIa within three months.
- Article 57 2bis makes it difficult to grant authorisations for any hazardous substances. Consider a new amendment. Substances that are adequately controlled should be authorised.

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